

**FIRST YEAR FELLOWS' SEMINAR
DEPARTMENT OF CLINICAL BIOETHICS
NATIONAL INSTITUTES OF HEALTH
2006-2007**

Wednesdays 4:00-5:30pm

- Fall: November 29, 2006-December 20, 2006
- Spring: January 24-June 20, 2007
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* = Supplemental reading

REQUIRED TEXTS

1. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 5th edition. New York: Oxford University Press, 2001.
2. Berg, Appelbaum, Lidz, Parker. Informed Consent, 2nd Edition. New York: Oxford University Press, 2001.
3. Daniels N. Just Health Care. New York: Cambridge University Press, 1985.
4. Dworkin G. The Theory and Practice of Autonomy. New York: Cambridge University Press, 1988.
5. Rawls JA. A Theory of Justice, Revised Edition. Cambridge, MA: Harvard University Press, 1999.
6. Levine RJ. Ethics and Regulation of Clinical Research. 2nd edition, New Haven: Yale University Press, 1988.
7. Julius B. Richmond and Rashi Fein, The Health Care Mess: How We Got Into It and What It Will Take To Get Out, Harvard University Press, 2005:
8. Faden R, Beauchamp TL. A History and Theory of Informed Consent. New York: Oxford University Press 1986.

November 29

HISTORY OF MEDICAL ETHICS

EMANUEL

1. Pellegrino ED. "The Metamorphosis Of Medical Ethics: A 30-Year Retrospective" JAMA 1993; 269:1158-1162.
2. Kass L. Is there a Medical Ethic? New York: Free Press, 1989. Chapter 9, 224-226
3. Beecher HK. "Ethics and Clinical Research." The New Eng J Med 1966; 274:1354-1360.
4. Vanderpool H. "A Critical Review of the Belmont Report"
5. Baker R. "From Medical Ethics into Bioethics: The Belmont Report and the Deprofessionalization of the Medical Ethics."
6. Emanuel E.J., The Evolving Norms of Medical Ethics

December 13

LEGAL CASES -- INFORMED CONSENT

SCHWARTZ

1. Katz, J. Chapter 3, pp 48-84. The Silent World of Doctor and Patient
1. Truman v. Thomas

2. Veatch, RM. Abandoning Informed Consent. Hastings Center Report 1995; 25:5-12
3. Berg, Appelbaum, Lidz, Parker. Chapter 3. Informed Consent, 2nd Edition. New York: Oxford University Press, 2001.
4. Canterbury v. Spence
5. Perna v. Pirozzi
6. Moore v. Regents of the University of California
7. Faya v. Almaraz
8. Johnson v. Kokemoor
9. Kaskie v. Wright
10. Hidding v. Williams
11. Culbertson v. Mernitz
12. Grimes v. Kennedy Krieger Institute

December 20

INFORMED CONSENT: ETHICS

WERTHEIMER

1. Beauchamp and Childress. *Principles of Biomedical Ethics*, 5th ed. Chapter 3, "Respect for Autonomy."
2. Berg, Lidz, Meisel. *Informed Consent*. Chapter 12, "Fulfilling the Underlying Purpose of Informed Consent."
3. Troug R, Robinson W, Randolph, A. "Is Informed Consent Always Necessary for Randomized, Controlled Trials?" *The New England Journal of Medicine* 1999; 340(10):804-807.

January 17, 2007

PRINCIPLISM

BEAUCHAMP

1. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 5th edition: read chap 1-2 & 8-9.

January 24

META ETHICS/ MORAL THEORY

RICHARDSON

1. Broome J, Weighing Goods, Chapter 1.
2. Dreier J, Structure of Normative Theories, *Monist* 96 (1993); 22-40
3. Kamm F, Non-consequentialism, the Person as an End-of-itself, and the significance of status, *Philosophy and Public Affairs* 21 (1992); 352-389
4. Richardson H, Beyond Good and Right: Toward a constructive Ethical Pragmatism, *Philosophy and Public Affairs* 24 (1995): 108-141

January 31

HEALTH CARE SYSTEM

FEIN

Please Read: Julius B. Richmond and Rashi Fein, The Health Care Mess: How We Got Into It and What It Will Take To Get Out, Harvard University Press, 2005: Chapters 2, 3, 5, 8 and such other Chapters as interest you..

*****Suggested readings:**

*Institute of Medicine, Care without Coverage: Too Little, Too Late, 2002.

*Institute of Medicine, A Shared Destiny: Community Effects of Uninsurance, 2003.

*Institute of Medicine, Hidden Costs, Value Lost: Uninsurance in America (2003)

*Institute of Medicine, Insuring America's Health: Principles and Recommendations (2004)

FEB 7

HEALTH CARE REFORM PROPOSALS

EMANUEL

1. Meyer JA, Wicks EK.. Covering America: Real Remedies for the Uninsured Economic and Social Research Institute, June 2001; Overview pg. 6-19.
2. Meyer JA, Wicks EK.. Covering America: Real Remedies for the Uninsured Vol #2 Economic and Social Research Institute, November 2003; Overview pg. 5-8.
3. Meyer JA, Wicks EK.. Covering America: Real Remedies for the Uninsured Vol #3 Economic and Social Research Institute, December 2003; Overview pg. 7-8.
4. Emanuel EJ., Fuchs VR, "Health Care Vouchers-A Proposal for Universal Coverage". NEJM 352; 12 (March 24, 2005) pg1255-1260.
5. Fuchs VR, Emanuel EJ, "Health Care Reform: Why? What? When?" Health Affairs vol 24:6, pp.1399-1414.
6. Physicians' Working Group, Proposal of the Physicians' Working Group for Single-Payer National Health Insurance. JAMA August 13, 2003 vol 290, No 6, pp798-805.
7. Gruber J, "The Massachusetts Health Care Revolution: A local Start for Universal Coverage,"Hastings Center Report 36, no.5 (2006):14-19.

February 14

JUSTICE IN HEALTH CARE

SREENIVASAN

1. N. Daniels, Just Health Care (Cambridge, 1985), chapters 2 and 3.
2. R. Dworkin, Sovereign Virtue (Harvard, 2000), ch. 8
3. G. Sreenivasan, "Health care and equality of opportunity," Hastings Center Report (forthcoming).

February 21

ALLOCATING SCARCE RESOURCES

DANIELS

1. Just Health (Cambridge U Press, forthcoming), Chapters 4, 10, 12

February 28

MANAGED CARE

PEARSON

1. Pearson SD. "Caring and Cost: The Challenge for Physician Advocacy." *Annals of Internal Medicine* 2000; 133(2):148-153.
2. Robinson JC. "The End of Managed Care." *JAMA* 2001; 285(20): 2622-2628.
3. Pearson SD, Sabin JE, Emanuel EJ. "No Margin, No Mission" Health-Care Organizations and the Quest for Ethical Excellence: Oxford University Press 2003; Chapter 5. Pp67-95.
4. Rosenthal MB, Market Watch: Doughnut-Hole Economics Insurance often serves purposes other than risk protection. *Health Affairs* 2004 vol 32, 6 pg. 129-135.

March 7**COST EFFECTIVENESS****MENZEL**

1. Asch DA, Jepson C, Hershey JC, Baron J, Ubel PA,; "When Money is saved by Reducing Healthcare Costs, Where Do U.S. Primary Care Physicians Think the Money Goes." American Journal of Managed Care, June 2003, pp. 438-442
2. Menzel P.; "Allocation of Scarce Resources," the Blackwell Guide to Medical Ethics (Rhodes, L Francis, and A. Silvers, eds.), Blackwell, December 2006, pp.305-322.
3. Ubel PA, Nord E, Gold M, Menzel P, Prades JLP, Richardson J, "Improving Value Measurement in Cost Effectiveness Analysis". Medical Care vol. 38 (9) pp. 892-901
4. Ubel PA, Loewenstein G, Jepson C., "Whose Quality of Life?"; "Commentary exploring discrepancies between health state evaluating of patients and the general public". Quality of Life Research (12) pp. 599-607 2003.

March 14**REFLECTIONS ON PUBLIC BIOETHICS****PELLINGRINO**

1. Kymlicka, W. "Moral Philosophy and Public Policy." Bioethics 1993; 7:1-26.
2. President's Council Executive Order 13237: November 28, 2001.
3. Gutmann A., Thompson D. Democracy and Disagreement. Cambridge, MA: Belknap Press, 1996, pp. 11-51.
4. The President's Council on Bioethics: "Human Cloning and Human Dignity: Policy Recommendations", chapter 8, pp. 1-17.
5. The President's Council on Bioethics: "Human Cloning and Human Dignity: Appendix – personal statements, pp. 1-43.
6. Warren, MA. Moral Status. Oxford: Clarendon Press, 1997, pp 1-23, and pages 148-177.
7. Pellegrino E, Bioethics and Politics: "Doing Ethics" in the Public Square, Journal of Medicine and Philosophy, 31:569-584, 2006.

March 21**PHYSICIAN-PATIENT RELATIONSHIP****EMANUEL**

1. Mechanic D and Schlesinger M. "The Impact of Managed Care on Patients' Trust in Medical Care and their Physicians." JAMA, 1996; 275:1693-1697.
2. Emanuel E and Dubler NN. "Preserving the Physician-Patient Relationship in the Era of Managed Care." JAMA, 1995; 273:323-329.
3. Emanuel E and Emanuel LL. "Four Models of the Physician-Patient Relationship." JAMA, 1992; 267:2221-2226.
4. "A Philosophical Reconstruction of Medical Morality" in ED Pellegrino and DC Thomasma, A Philosophical Basis of Medical Practice (NY: Oxford U Press, 1981), pp. 192-220.
5. Sulmasy DP, Bloche MG, Mitchell J, Hadley J. Physicians' ethical views about cost-containment methods. *Arch Intern Med* 2000;160: 649-657.

March 28**CAM PRACTICE AND RESEARCH****TILBURT**

1. Kaptchuk TJ, Eisenberg DM. Varieties of healing, 1: Medical pluralism in the United States: Annals of Internal Medicine 2001; 135:189-985.

2. Miller FG, Emanuel EJ, Rosenstein DL, Straus SE. Ethical issues concerning research on complementary and alternative medicine. JAMA 2004;291:599-604.
3. Barry CA, The Role of Evidence in alternative Medicine: Contrasting biomedical and anthropological approaches; Social Science and Medicine 2005, pp1-12.

*****suggested additional readings**

Kaptchuk TJ, Eisenberg DM. The persuasive appeal of alternative medicine. Annals of Internal Medicine 1998; 129: 1061-65.

Ernst EJ, Cohen MH. Informed consent in complementary and alternative medicine. Arch Intern Med 2001;161:2288-92.

Adams KE, Cohen MH, Eisenberg D, Jonsen AR. Ethical considerations of complementary and alternative medical therapies in conventional medical settings. Ann Intern Med 2002;137:660-4.

Kaptchuk TJ. The placebo effect in alternative medicine: can the performance of a healing ritual have clinical significance? Ann Intern Med 2002;136:817-25.

Kaptchuk TJ, Miller FG. What is the best and most ethical model for the relationship between mainstream and alternative medicine: opposition, integration or pluralism? Academic Medicine, 2005;80:286-90

April 11

ETHICS CONSULTATION

DANIS

1. Casarett DJ, Daskal F, Lantos J “Experts in Ethics?: The Authority of the Clinical Ethicist”, Hastings Center Report 28 vol.6 (1998):6-11.
2. Fletcher JC, Siegler M, “What are the Goals of Ethics Consultation: A Consensus Statement, The journal of Clinical Ethics, Summer 1996, vol. 7, 2:pp122-126.
3. Moreno JD, Ethics by Committee: “The Moral Authority of Consensus”, The Journal of Medicine and Philosophy 13 (1988): pp.411-432.
4. Urban Walker M, Keeping Moral Space Open: New Images of Ethics Consulting, Hastings Center Report, March-April 1993, pp.33-40
5. Ross JW, John MA, Glaser JW, S.T.D., et al, Case Consultation and Review: Matching Skills and Expectations. Chapter 7 pg; 91-107
6. Wolf SM, “Toward a Theory of Process”, Law, Medicine and Health Care vol. 20:4 (1992) 278-290.
7. Ausulio MP, Arnold RM, Younger SJ, “Health Care Ethics Consultation: Nature, Goals, and Competencies”. Annals of Internal Medicine 2000; 133: 59-69

April 18

LEGAL CASES-TERMINATING TREATMENT

FORSTER

1. Cruzan v. Director Missouri Department of Health
2. Quinlan v Supreme Court of New Jersey
3. Brophy v. New England Sinai Hospital, Inc.
4. Annas George J, “Culture of life” politics at the bedside – The Case of Terri Schiavo, NEJM 2005

April 24

ABORTION

LITTLE

1. Little M, "The Morality of Abortion," A Companion to Applied Ethics, eds. Christopher Wellman and Ray Frey (Blackwell, 2003).

May 2

ORGAN TRANSPLANTATION

VEATCH

1. Veatch R. "Egalitarian and Maximum Theories of Justice: Directed Donation of Organs for Transplant", Journal of Medicine and Philosophy 23 (3, 1998): 456-476.

May 9

STEM CELL RESEARCH

MORENO

1. National Bioethics Advisory Council; Ethical issues in Stem Cell Research Sept 1999, executive summary and chapter 4.
2. Stem Cells and the Future of Regenerative Medicine
<<http://www.nap.edu/books/0309076307/html/>> - a 2002 Executive summary and Chapter 4.
3. The NEJM Perspective article on the Korean Stem Cell Hub Project (10/20/2005)
4. National Academies Press; Guidelines Human Embryonic Stem Cell Research 2005, Summary and Chapter 6.

****suggested additional readings:**

The NAS Guidelines for Human Embryonic Stem Cell Research (2005)
<http://www.nap.edu/books/0309096537/html/>

May 16

ANIMAL EXPERIMENTATION

DEGRAZIA

1. DeGrazia, D. Chapter 3: "Animals' moral status and the issue of equal consideration", pp 36-74 Taking Animals Seriously: Mental Life and Moral Status (Cambridge: Cambridge University Press, 1996).
2. DeGrazia, D. "The Ethics of Animal Research: What Are the Prospects for Agreement?" Cambridge Quarterly of Healthcare Ethics, 1999; 8:23-34.
3. Brody, B. "Defending Animal Research: An International Perspective" pp 426-436 in Contemporary Issues in Bioethics, 6th Ed., Tom L. Beauchamp and LeRoy Walters, eds. (Belmont, CA: Wadsworth, 2003).
4. DeGrazia, D. Chapter 7: "Animal Research," pp. 98-125 in Animal Rights: A Very Short Introduction (Oxford: Oxford University Press, 2002).
5. DeGrazia D. "On the Ethics of Animal Research," in Richard Ashcroft (ed.), *Principles of Health Care Ethics* (West Sussex, UK: Wiley & Sons, forthcoming 2007).

May 23**CONFLICT OF INTEREST****GROSS**

1. Chaudhry S, Schroter S, Smith R, Morris J. "Does Declaration of competing interests affect readers' perceptions?" A randomized trial. *BMJ* 2002; vol. 325 pp1391-2.
2. Steinbrook R. Conflicts of Interest at the NIH — Resolving the Problem., *N Engl J Med* 2004; 351:955-957, Sep 2, 2004.
3. Bekelman JE, Li Y, Gross GP. "Scope and Impact of Financial Conflicts of Interest in Biomedical Research". *JAMA* 2003, v.289 #4, pp.454-465.
4. Bero LA, Glantz S, Hong MK. "The Limits of competing interest disclosures", *Tobacco Control* 2005; 14; 118-126
5. Mello MM, Phil M, Clarridge BR, Studdert DM; Academic Medical Centers Standards for Clinical-Trial agreements with Industry. *NEJM* 352; 21; 2202-10.
6. Turner EH, A taxpayer-Funded Clinical Trials Registry and Results Database- It already exists with the US Food and Drug Administration. *PLoS Medicine* 12/2004; vol 1; issue 3: 180-2.

May 30**GENETIC TESTING****HULL**

1. John Robertson, "The \$1,000 genome: ethical and legal issues in whole genome sequencing of individuals" *American Journal of Bioethics* 3(3) InFocus (<http://www.bioethics.net>).
2. Wilfond BS, Nolan K. National policy development for the clinical application of genetic diagnostic technologies. Lessons from cystic fibrosis. *JAMA*. 1993 Dec 22-29; 270(24):2948-54.
3. Clayton et al. Informed consent for genetic research on stored tissue samples. *JAMA* 1995;274:1786
4. Eric Juengst, "Caught in the middle again: Professional ethical considerations in genetic testing for health risks," *Genetic Testing* 1;3 (1997/98): 189-200.

June 6**PUBLIC HEALTH****KASS**

1. Wikler, D. "Persuasion and Coercion for Health: Ethical Issues in Government Efforts to Change Lifestyles." *Milbank Quarterly*, 1978; 56(3):303-333.
2. Pellegrino, E.D. "Health Promotion as Public Policy: The Need for Moral Groundings." *Preventive Medicine*, 1981; 10:371-378.
3. Kass, N.E. "An Ethics Framework for Public Health." *American Journal of Public Health*, 2001; 91:1776-1782.
4. Callahan, D. and Jennings, B. "Ethics and Public Health: Forging a Strong Relationship." *American Journal of Public Health*, 2002; 92(2):169-176.
1. Childress, J.F., Faden, R.R., Gaare, R.D., Gostin, L.O., Kahn, J., Bonnie, R.J., Kass, N.E., Mastroianni, A.C., Moreno, J.D., and Nieburg, P. "Public Health Ethics: Mapping the Terrain." *Journal of Law, Medicine, and Ethics*, 2002; 30:170-178

June 13

GENETIC ENHANCEMENT

HEYD

2. DeGrazia D, Enhancement Technologies and Human Identity; *Journal of Medicine and Philosophy* 30 (2005): 261-283
5. Juengst ET, "What Does Enhancement Mean?"; in E. Parens (ed.), *Enhancing Human Traits: Ethical and Social Implications* (Washington D.C.: Georgetown University Press, 1998), pp. 29-47..

June 20

EUTHANASIA/PAS

QUILL

1. Hedberg K, Hopkins D, Kohn M. "Five Years of Legal Physician-Assisted Suicide in Oregon." *NEJM*, 2003; 348(10): 961-964.
2. Quill TE, Meier DM, Block SD, Billings JA. "The Debate Over Physician-Assisted Suicide. Empirical Data and Convergent Views." *Annals of Internal Medicine* 1998; 128:552-558.

Suggested reading:

DHS/Oregon –Death with Dignity Act—copy of web page is included.